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22907 BANNER & W	7590 07/03/200 ITCOFF, LTD.	EXAMINER		
1100 13th STRI		WILDER, CYNTHIA B		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)
	10/743,384	ROTHMAN ET AL.
Office Action Summary	Examiner	Art Unit
	CYNTHIA B. WILDER	1637
The MAILING DATE of this communication ap Period for Reply	opears on the cover sheet with the o	correspondence address
A SHORTENED STATUTORY PERIOD FOR REP WHICHEVER IS LONGER, FROM THE MAILING I - Extensions of time may be available under the provisions of 37 CFR 1 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory perio- Failure to reply within the set or extended period for reply will, by statu Any reply received by the Office later than three months after the mail earned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNICATION  .136(a). In no event, however, may a reply be tilt  d will apply and will expire SIX (6) MONTHS from the, cause the application to become ABANDONE	N. mely filed the mailing date of this communication. ED (35 U.S.C. § 133).
Status		
1)☐ Responsive to communication(s) filed on <u>04</u> .  2a)☑ This action is <b>FINAL</b> . 2b)☐ Th  3)☐ Since this application is in condition for allow closed in accordance with the practice under	is action is non-final. ance except for formal matters, pro	
Disposition of Claims		
4)  Claim(s) 1-42 is/are pending in the applicatio 4a) Of the above claim(s) is/are withdres 5)  Claim(s) is/are allowed. 6)  Claim(s) 1-42 is/are rejected. 7)  Claim(s) is/are objected to. 8)  Claim(s) are subject to restriction and/	awn from consideration.	
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<ul> <li>9) The specification is objected to by the Examir</li> <li>10) The drawing(s) filed on is/are: a) ac</li> <li>Applicant may not request that any objection to the Replacement drawing sheet(s) including the corre</li> <li>11) The oath or declaration is objected to by the E</li> </ul>	ccepted or b) objected to by the e drawing(s) be held in abeyance. Se ction is required if the drawing(s) is ob	e 37 CFR 1.85(a). ejected to. See 37 CFR 1.121(d).
Priority under 35 U.S.C. § 119		
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:     1. Certified copies of the priority document 2. Certified copies of the priority documents. Copies of the certified copies of the priority documents. See the attached detailed Office action for a list	nts have been received. nts have been received in Applicat ority documents have been receiv au (PCT Rule 17.2(a)).	ion No ed in this National Stage
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date	4)  Interview Summary Paper No(s)/Mail D 5)  Notice of Informal F 6)  Other:	ate

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## **DETAILED ACTION**

1. Applicant's amendment filed 4/4/2008 is acknowledged and has been entered.

Claims 1-3 and 16 have amended. Claims 43-52 have been canceled. Claim 1-42 are

pending. All of the arguments have been thoroughly reviewed and considered but are

not found persuasive for the reasons discussed below. Any rejection not reiterated in

this action has been withdrawn as being obviated by the amendment of the claims.

#### This action is made FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

# **Previous Rejection**

3. The prior art rejections under 35 USC 112 second paragraph is withdrawn in view of applicant's amendment. The prior art rejections under 35 USC 103(a) maintained and discussed below.

## Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Once again, Claims 1-3, 7-11, 13-18, 22-26 and 28-42 are rejected under 35 6. U.S.C. 103(a) as being unpatentable over Greisen et al (Journal of Clinical Microbiology, vol. 32, no. 2, pages 335-351, Feb. 1994) and Reischl et al (Journal of Clinical Microbiology, Vol. 38, No. 6, pages 2429-2433, June 2000). Regarding claims 1-3, 16-18 and 33-42. Greisen et al teach a method for detecting eubacterial and determining species of said eubacteria in a sample, comprising: providing universal bacterial primers that correspond to regions of the 16S rRNA gene which are highly conserved among divergent groups of eubacteria and therefore would be expected to amplify DNA from most pathogenic bacteria; providing universal bacterial probe designed from a conserved region of the 16S rRNA gene, which is located between the universal primers (see pages 340-341, sections entitled "Specificity of universal bacterial primers" and "Universal bacterial probe" and "Universal gram-positive and gram-negative probes") and performing DNA amplification (page 336, section entitled "DNA amplification") and probe hybridization (page 338). Greisen et al teach that the primers locations were chosen to be relatively specific for eubacterial genes at the 3' ends (page 341). Thus Greisen inherently meet the limitations of the claims for the conserved and divergent regions of the eubacterial species as recited in the claims.

The bindings to the various divergent regions are deemed inherent by the universal primers and probes of Greisen et al.

Greisen et al do not expressly teach wherein the universal primers and universal probes are used in real-time fluorescence PCR. Reischl et al teach a duplex LightCycler PCR assay to detection of Staphylococcus aureus strains and other related bacterial species (abstract). Reischl et al teach wherein the method comprises providing oligonucleotide primers and fluorescence-labeled hybridization probes, designed for amplification and sequence-specific detection of fragments within mecA and S. aureus specific genomic markers (page 2430, col. 2). Reischl et a teach that this duplexes approach, containing four different primers oligonucleotides and four different hybridization probes within a single capillary, revealed identical detection limits. Reischl et al teach that significant formation of primer dimers or secondary structures or other cross-reactions between oligonucleotide components, which frequently interfere with the analytical sensitivity of multiplex PCR approaches are therefore unlikely in this particular assay (bottom of page 2432, col. 2 bridging page 2432, col. 1 first five lines). Reischl et al further teach that the LightCycler device used in the method allows for ultrarapid thermal cycling and online monitoring of the amount of specific PCR products present in an amplification mixture (page 2429, col. 2, lines 14-17).

Reischl et al teach that the LightCycler HybProbe concept avoids the application of time-consuming and laborious post-amplification procedures (bottom of page 2432, col. 1). Reischl et al teach that due to its compact and reliable nature, the duplex PCR assay proved to be a valuable tool for the rapid identification of *S. aureus* isolates in the

environment of a routine microbiological laboratory setting 9bottom of page 2432, col. 1 to top of col.2). Reischl et al teach that in combination with the simple boiling protocol for template DNA preparation, it can be easily integrated into the workflow of any diagnostic laboratory (page 2432, col. 2).

Therefore, one of ordinary skill in the art would have been motivated to have modified the PCR eubacterial speciation method of Greisen to encompass a real-time fluorescence PCR method as taught by Reischl instead of the traditional PCR amplification reaction based on the numerous advantages taught by Reischl et al that the LightCycler PCR assay allows for ultra-rapid thermal cycling and online monitoring of the amount of specific PCR products present in an amplification mixture, the method alleviates significant formation of primer dimers or secondary structures or other cross-reactions between oligonucleotide components and the method avoids the application of time-consuming and laborious post-amplification procedures.

Regarding claim 7-8, 10-11, 22-23 and 25-26, Greisen et al teach wherein the sample is for the detection of bacteria in blood, cerebrospinal fluid and other normally sterile body fluids, which includes urine (page 335, col. 2, last 6 lines).

Regarding claims 9 and 24, Greisen et al teach wherein the sample was treated to extract DNA from cells (see page 336, "DNA Isolation").

Regarding claims 13-15, 28-30, Reischl et al teach wherein the segment amplified is about 179 base pairs (see page 2430, col. 2).

Regarding claim 31 and 32, Greisen et al inherently teach wherein the conserved region is at least 80% identical in over 14 eubacterial species (see page 340 and 345 and Table 2).

7. Once again, Claims 4, 12, 19 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greisen et al in view of Reischl et al as previously applied above, in view of Abrams et al (6238927, effective filing date October 1998) and Iversen (6677153, effective filing date November 1999) and further in view of Buck et al (Biotechniques vol. 27, No. 3, pages 528-536, 1999). Regarding claims 4, 12, 19 and 27, Greisen et al in view of Reischl et al teach a method for detecting and determining species of eubacteria in a sample use a real time fluorescence PCR assay as previously described above.

The method of Greisen et al in view of Reischl et al differs from the instant invention in that the references do not expressly teach wherein the segment of S. aureus 16 rRNA gene comprises the nucleotides as shown in SEQ ID NO: 1 and 2.

Abrams et al teach a primer sequence that is 100% identical to the sequence of SEQ ID NO: 1 (see SEQ ID NO: 1 at col. 13 and 14), wherein said sequence is used in a method for detection of a target nucleic acid sequence.

Iversen teaches a primer sequence that is 100% identical to the sequence of SEQ ID NO: 2 (see SEQ ID NO: 25 at col. 63 and 64), wherein said sequence is used in a method for detection of a target nucleic acid sequence.

In the recent court decision In Re Deuel 34 USPQ 2d 1210 (Fed. Cir. 1995), the

Court of Appeals for the Federal Circuit determined that the existence of a general method of identifying a specific DNA does not make the specific DNA obvious. Regarding structural or functional homologs, however, the Court stated,

"Normally, a *prima facie* case of obviousness is based upon structural similarity, i.e., an established structural relationship between a prior art compound and the claimed compound. Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties (see page 9, paragraph 4 of attached ref)."

Since the claimed primers and probes simply represent structural homologs of the oligonucleotides taught by Abrams et al and Iversen, which are 100% derived from sequences expressly suggested by the prior art of and known in the prior art as useful for primers and probes for detecting a specific target, and concerning which a biochemist of ordinary skill would attempt to obtain alternate compounds with improved properties, the claimed primers and probes are *prima facie* obvious over the cited references in the absence of secondary considerations.

With regard to the issue of equivalence of the primers, MPEP 2144.06 notes "Substituting equivalents known for the same purpose. In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the

components at issue are functional or mechanical equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982)."

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With regard to the issue of reasonable expectation of success in using such equivalents, Buck et al expressly provides a general teaching of evidence of the equivalence of primers. Specifically, Buck invited primer submissions from a number of labs (39) (page 532, column 3), with 69 different primers being submitted (see page 530, column 1). Buck also tested 95 primers spaced at 3 nucleotide intervals along the entire sequence at issue, thereby testing more than 1/3 of all possible 18-mer primers on the 300 base pair sequence (see page 530, column 1). When Buck tested each of the primers selected by the methods of the different labs, Buck found that EVERY SINGLE PRIMER worked (see page 533, column 1). Only one primer ever failed, No. 8, and that primer functioned when repeated. Further, EVERY SINGLE CONTROL PRIMER functioned as well (see page 533, column 1). Buck expressly states "The results of the empirical sequencing analysis were surprising in that nearly all of the primers yielded data of extremely high quality (page 535, column 2)." Therefore, Buck provides direct evidence that all primers would be expected to function, and in particular, all primers selected according to the ordinary criteria, however different, used by 39 different laboratories. It is particularly striking that all 95-control primers functioned, which represent 1/3 of all possible primers in the target region.

This clearly shows that every primer would have a reasonable expectation of

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success.

8. Once again, claims 5 and 20 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Greisen et al in view of Reischl et al as previously applied above, in

view of Kunsch et al (6593114, effective filing date January 1996) and further in view of

Buck et al (Biotechniques vol. 27, No. 3, pages 528-536, 1999). Regarding claims 5

and 20, Greisen et al in view of Reischl et al teach a method for detecting and

determining species of eubacteria in a sample use a real time fluorescence PCR assay

as previously described above.

The method of Greisen et al in view of Reischl et al differs from the instant

invention in that the references do not expressly teach wherein the segment of S.

aureus 16 rRNA gene comprises the nucleotides as shown in SEQ ID NO: 3.

Kunsch et al teach a sequence that is 95.7% identical to the sequence of SEQ ID

NO: 3:

SEQ ID NO: 3

CACGAGCTGACGACARCCATGCA

Kunsch et al (SEQ ID NO: 5124)

CACGAGCTGACGACAACCATGCA, wherein

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said sequence is used to detect *S. aureus* strains.

In the recent court decision In Re Deuel 34 USPQ 2d 1210 (Fed. Cir. 1995), the

Court of Appeals for the Federal Circuit determined that the existence of a general

method of identifying a specific DNA does not make the specific DNA obvious.

Regarding structural or functional homologs, however, the Court stated,

"Normally, a prima facie case of obviousness is based upon structural similarity, i.e., an

established structural relationship between a prior art compound and the claimed compound. Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties (see page 9, paragraph 4 of attached ref)."

Since the claimed primers and probes simply represent structural homologs of the oligonucleotides taught by Kunsch et al, which is 95.7% identical to and derived from sequences expressly suggested by the prior art and known in the prior art as useful for primers and probes for detecting a specific target, such as *S. aureus*, and concerning which a biochemist of ordinary skill would attempt to obtain alternate compounds with improved properties, the claimed primers and probes are *prima facie* obvious over the cited references in the absence of secondary considerations.

With regard to the issue of equivalence of the primers, MPEP 2144.06 notes "Substituting equivalents known for the same purpose. In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA)

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1982)."

With regard to the issue of reasonable expectation of success in using such equivalents, Buck et al expressly provides a general teaching of evidence of the equivalence of primers. Specifically, Buck invited primer submissions from a number of labs (39) (page 532, column 3), with 69 different primers being submitted (see page 530, column 1). Buck also tested 95 primers spaced at 3 nucleotide intervals along the entire sequence at issue, thereby testing more than 1/3 of all possible 18-mer primers on the 300 base pair sequence (see page 530, column 1). When Buck tested each of the primers selected by the methods of the different labs. Buck found that EVERY SINGLE PRIMER worked (see page 533, column 1). Only one primer ever failed, No. 8, and that primer functioned when repeated. Further, EVERY SINGLE CONTROL PRIMER functioned as well (see page 533, column 1). Buck expressly states "The results of the empirical sequencing analysis were surprising in that nearly all of the primers yielded data of extremely high quality (page 535, column 2)." Therefore, Buck provides direct evidence that all primers would be expected to function, and in particular, all primers selected according to the ordinary criteria, however different, used by 39 different laboratories. It is particularly striking that all 95-control primers functioned, which represent 1/3 of all possible primers in the target region.

This clearly shows that every primer would have a reasonable expectation of success.

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Claim Rejections - 35 USC § 103

9. Claims 6 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Greisen et al in view of Reischl et al as previously applied above, in view of Barry et al

(EP 0 395 295) and further in view of Buck et al (Biotechniques vol. 27, No. 3, pages

528-536, 1999). Regarding claims 4, 12, 19 and 27, Greisen et al in view of Reischl et

al teach a method for detecting and determining species of eubacteria in a sample use

a real time fluorescence PCR assay as previously described above.

The method of Greisen et al in view of Reischl et al differs from the instant

invention in that the references do not expressly teach wherein the segment of S.

aureus 16 rRNA gene comprises the nucleotides as shown in SEQ ID NO: 4

Barry et al teach an S. aureus probe sequence that is 100% identical to the

sequence of SEQ ID NO: 4 (see alignment below).

SEQ ID NO: 4 1 CCTTTGACAACTCTAGAGATAGAGCCTTCCC 31

EP 0395295 13 CCTTTGACAACTCTAGAGATAGAGCCTTCCC 43.

In the recent court decision In Re Deuel 34 USPQ 2d 1210 (Fed. Cir. 1995), the

Court of Appeals for the Federal Circuit determined that the existence of a general

method of identifying a specific DNA does not make the specific DNA obvious.

Regarding structural or functional homologs, however, the Court stated,

"Normally, a prima facie case of obviousness is based upon structural similarity, i.e., an

established structural relationship between a prior art compound and the claimed

compound. Structural relationships may provide the requisite motivation or suggestion

to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties (see page 9, paragraph 4 of attached ref)."

Since the claimed primers and probes simply represent structural homologs of the oligonucleotides taught by Barry et al, which is 100% derived from sequences expressly suggested by the prior art of and known in the prior art as useful for primers and probes for detecting a specific target, and concerning which a biochemist of ordinary skill would attempt to obtain alternate compounds with improved properties, the claimed primers and probes are *prima facie* obvious over the cited references in the absence of secondary considerations.

With regard to the issue of equivalence of the primers, MPEP 2144.06 notes "Substituting equivalents known for the same purpose. In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982)."

This clearly shows that every primer would have a reasonable expectation of success.

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# Response to Arguments

10. Applicant traverses the rejections on the following grounds: Applicant summarizes the Examiner's rejection and states that one of ordinary skill in the art could not have known from the cited references that real-time PCR would work properly when two probes must hybridize to the same amplified segments. With regard to Reischl, Applicant states that Reischl does not address whether one could successfully use the real time PCR assay successfully perform the method of the present invention, using a single set of primers, a single amplicon and multiple probes (e.g., second, third and fourth probes). Applicant contends that Reischl does not teach whether this could be done using a eubacterial 16S rRNA gene. Applicant argues that Reischl provides support for the unpredictability that surrounds real-time PCR assays in general. Applicant argues that one of ordinary skill in the art would not have had a reasonable expectation of success even if they were motivated to try the present invention. Applicant provides an exhibit citing Corless as evidence of the state of the art at the time of the instant invention. Applicant states that Corless teaches that there were technical issues evident with the type of approach the present Applicant's ultimately employed. Applicant further argues that Corless was so discouraged by the technical problems that he moved on to a system for the same purpose that did not use 16S rRNA genes at all. Applicant concludes that the publications of Corless provide a picture of the state of the art around the time of the invention. Applicant states that given the state of the art, the solution found by the present applicants was not obvious.

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11. All of the arguments have been thoroughly reviewed and considered but are not found persuasive. Specifically, Applicant's arguments do not commensurate in scope with the claims as currently written. Firstly, it appears that Applicant is arguing efficiency, superiority and sensitivity of the method of the instant invention when in fact no efficiency, superiority or sensitivity has been claimed by the instant claims. MPEP states that "[A] known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994)". In this case, the claims are merely drawn to a real-time PCR reaction al taught by Reischl using the primer and probe conditions taught by the primary reference of Greisen et al. The claims in no way require that the results of the reaction have a required or even desired sensitivity or be operable without any contamination or with high sensitivity. While the Examiner acknowledges Applicant's Exhibit discussing the result of Corless, the teachings of Corless does not suggest that the combination of Greisen in view of Reischl would render an inoperable method. Rather the teachings of Corless only suggest that the method may result in products with reduce sensitivity, which is not exclude from the claims. Therefore, this argument is not found persuasive.

Secondly, Applicant appears to argue that they have successfully demonstrated using competing probes (e.g., third and fourth probes) which compete for the same stretch of DNA in a real-time PCR reaction. However, it is noted that while the specification teaches that multiple probes (e.g., a third and fourth probe) may exist and may be encompassed by the instant invention, Applicant does not successfully

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demonstrate their use in a real-time PCR reaction. The specification only demonstrates via example the successful use of two fluorogenic probes in the amplification reactions (see figures 1-4). Thus, this argument is not found persuasive.

Finally, in regards to applicant's arguments that Corless recognizes the unpredictability in the art at the time of the instant invention, Applicant is again reminded that this argument is not commensurate in scope with the claims as currently written as the claims do not require that the method be performed without contamination or with high specificity, as was objective of Corless. The examiner maintains that Reischl provides sufficient motivation for one of ordinary skill in the art at the time of the claimed invention to attempt the real-time PCR process using the universal primers and probes as taught by Greisen with predictable result, irregardless of its sensitivity as the claims do not require such features. Attention is also directed to KSR Int'l Co. v. Teleflex Inc. (550 U.S., 127 S. Ct. 1727 (2007)) where the Supreme Court determined that "a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103 (KSR, 550 U.S. at , 82 USPQ2d at 1397)." The Supreme Court also determined that "[t]he combination of familiar elements according to known methods is likely to be obvious when the combination does no more than yield predictable results (KSR, 550 U.S. at , 82 USPQ2d at 1395)." In view of foregoing, the rejections under 35 USC 103(a) are maintained.

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#### Conclusion

12. No claims are allowed. **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CYNTHIA B. WILDER whose telephone number is (571)272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/cbw/

/Teresa E Strzelecka/ Primary Examiner, Art Unit 1637

July 1, 2008